

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/682,289	Confirmation No.:	9339
Applicant(s):	F. Barry Bays, et al.		
Filed:	October 9, 2003		
Art Unit:	1651		
Examiner:	Ruth A. Davis		
Title:	Bone Marrow Infusion Chamber and Method		

Docket No.: 702.113

Customer No.: 37902

FILED ELECTRONICALLY

Mail Stop Appeal Brief-Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

SECOND APPEAL BRIEF UNDER 37 CFR § 41.37

This Appeal Brief is filed pursuant to the April 10, 2008 Notice of Appeal to the Board of Patent Appeals and Interferences.

1. *Real Party in Interest*

The real party in interest in this appeal is Wright Medical Technology, Inc., the assignee of the above-referenced patent application.

2. *Related Appeals and Interferences*

There are no related appeals or interferences involving this application or its claimed subject matter.

3. *Status of Claims*

Claims 23-44 are pending. Claims 1-22 are cancelled. No other claims are pending. All claims stand rejected as unpatentable over a combination of prior art references as set forth in greater detail below. The prior art rejection of all pending claims is appealed herein.

4. *Status of Amendments*

All amendments have been entered.

5. *Summary of Claimed Subject Matter*

The invention is an apparatus for preparing a bone graft composite comprising a bone graft material **M** and a bone marrow aspirate **A**. The invention allows the bone graft material **M** and the bone marrow aspirate **A** to be mixed (i.e. infused) in the operating room. (**Specification, p. 10, lines 2-4; page 14, lines 12-14**). In the embodiment of independent **Claim 23**, the apparatus comprises a tube **10** having a first open end **12** and a second open end **14**. (**Figure 2; Specification, p. 8, lines 16-19, p. 10, lines 6-7**). A first end cap **16** (also designated as end cap **44** in **Figure 3**) is removably coupled to the first open end **12**. (**Figure 3; Specification, p. 11, lines 3-4**). The first end cap **16** has a passage therethrough to allow fluid communication between a bone marrow aspirate delivery member **100** and the tube **10**. (**Figures 3 and 6B**). A trailing end **48** of the end cap **16** (designated end cap **44** in **Figure 3**) is configured for selective attachment to a bone marrow aspirate delivery member, such as a syringe **100**. (**Figures 1, 3, 6A, 6B; Specification, p. 11, line 31-p. 12, line 2**). A second end cap **18** is removably coupled to the second end **14**. (**Figure 2; Specification, p. 11, lines 3-4**). The second end cap **18** has a passage therethrough to allow fluid communication between the tube **10** and a filter **50**. (**Figures 2, 3, 4, 6B and 7; Specification, p. 12, line 28-p. 13, line 2**). A leading end **48** of the second end cap **18** is configured for selective attachment of a filter **50**. (**Figure 2; Specification, p. 11, lines 6-7; p. 11, line 31-p. 12, line 2**). A filter member **20** is removably coupled to the leading end **48** of the second end cap **18**. (**Figures 1 and 2; Specification, p. 11, lines 6-7 and p. 11, line 31-p. 12, line 2**). As shown in **Figure 4**, a filter **50** is in the filter member **20**. (**Figure 4**). The filter **50** is

configured to prevent bone marrow aspirate **M** from passing therethrough while permitting air to pass therethrough. (**Figures 6B and 7; Specification, p. 11, lines 9-12, p. 12, lines 3-5, p. 13, lines 1-2**). The filter is in fluid communication with the tube **10** via the passage of the second end cap **18**. (**Figures 2, 3, 4, 6B and 7; Specification, p. 12, line 28-p. 13, line 2**). The tube **10** contains a bone graft material **M**. (**Figure 1; Specification, p. 10, lines 11-13**).

In dependent **claim 24**, which depends from **claim 23**, the bone graft material **M** is selected from the group consisting of calcium sulfate, calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix. (**Specification, p. 10, lines 14-21**). In dependent **claim 25**, which depends from independent **claim 23**, the bone graft material comprises tri-calcium phosphate. (**Specification, p. 10, lines 14-16**). Dependent **claim 26**, which depends from independent **claim 23**, specifies that the bone graft material **M** is porous to bone marrow aspirate. (**Figure 1; Specification, p. 10, lines 14-15 and 23-28**). Dependent **claim 27**, which depends from independent **claim 23**, specifies that the bone graft material comprises a plurality of small pieces of bone graft material. (**Figure 1; Specification, p. 10, lines 23-28**).

Dependent **claim 28**, which depends from independent **claim 23**, further comprises the first end cap **16** sealed by a removable first sealing cap **22** on a trailing end of the first end cap **16**. (**Figures 1-2; Specification, p. 11, lines 8-9**). Dependent **claim 29**, which depends from dependent **claim 28**, further comprises the filter member **20** sealed by a removable second sealing cap **24** on a leading end of the filter member **20**. (**Figures 1-2; Specification, p. 11, lines 8-9**).

Dependent **claim 30**, which depends from dependent **claim 23**, further comprises a first washer **38** disposed between the first end cap **16** and the first end **12** of the tube **10**. (**Figure 2; Specification, p. 11, lines 23-26**). Dependent **claim 31**, which depends from dependent **claim 30**, further comprises a second washer **40** disposed between the second end cap **18** and the second end **14** of the tube **10**. (**Figure 2; Specification, p. 11, lines 23-26**).

Dependent **claim 32**, which depends from dependent **claim 25**, further specifies that the bone graft material **M** comprises a plurality of small pieces of bone graft material **M**. (**Figure 1; Specification, p. 10, lines 23-28**). Dependent **claim 33**, which depends from dependent **claim 32**, further comprises a first washer **38** disposed between the first end cap **16** and the first end **12** of the tube **10**, and a second washer **40** disposed between the second end cap **18** and the second end **14** of the tube **10**. (**Figure 2; Specification, p. 11, lines 23-26**). Dependent **claim 34**, which depends from dependent **claim 33**, further comprises the first end cap **16** sealed by a removable first sealing cap **22** on a trailing end of the first end cap **16**. (**Figure 2; Specification, p. 11, lines 8-9**).

Dependent **claim 35**, which depends from dependent **claim 24**, further comprises the filter member **20** sealed by a removable second sealing cap **24** on a leading end of the filter member **20**. (**Figure 2; Specification, p. 11, lines 8-9**). Dependent **claim 36**, which depends from independent **claim 23**, further comprises bone marrow aspirate **A** in the tube **10**, the bone marrow aspirate **A** having been introduced into the tube **10** through the first end **12** of the tube **10**, and air having been expelled through the filter **50** of the filter member **20** to facilitate introduction of the bone marrow aspirate **A** into the tube **10**. (**Figures 6B and 7; Specification, p. 12, line 25-p. 13, line 2**).

Dependent **claims 37-39** depend from dependent **claim 36**. Dependent **claim 37** further specifies that the bone marrow aspirate **A** has been allowed to coagulate in the tube **10** while in contact with the bone graft material **M**. (**Specification, p. 13, lines 16-20**). Dependent **claim 38** specifies that the bone graft material **M** is substantially saturated with the bone marrow aspirate **A**. (**Specification, p. 10, lines 24-26, p. 16, lines 17-18**). Dependent **claim 39** further comprises coupling a second sealing cap **24** to the filter member **20** to thereby provide a relatively air tight environment after air has been expelled from the tube **10**. (**Figure 2; Specification, p. 11, lines 8-9**).

Dependent **claims 40-44** present a series of nested claims. Dependent **claim 40**, which depends from dependent **claim 36**, further specifies that the bone graft material **M** comprises tri-calcium phosphate. (**Specification, p. 10, lines 14-16**). Dependent **claim 41**, which depends in series from dependent **claims 23, 36, and 40**, further comprises a first washer **38** disposed between the first end cap **16** and the first end **12** of the tube **10**. (**Figure 2; Specification, p. 11, lines 23-26**). Dependent **claim 42**, which depends in series from **claims 23, 36, 40 and 41**, further comprises a second washer **40** disposed between the second end cap **18** and the second end **14** of the tube **10**. (**Figure 2; Specification, p. 11, lines 23-26**). Dependent **claim 43**, which depends in series from **claims 23, 36, and 40-42**, specifies that the trailing end of the first end cap **16** that is configured for attachment to a bone marrow aspirate delivery member **100** is further specifically configured for attachment to a syringe **100**. (**Figure 6B; Specification, p. 11, line 31-p. 12, line 2**). Dependent **claim 44**, which depends in series from **claims 23, 36, and 40-43**, further comprises coupling a second sealing cap **24** to the filter member **20** to thereby

provide a relatively air tight environment after air has been expelled from the tube **10**. (**Figure 2; Specification, p. 11, lines 8-9, p. 13, lines 10-15**).

6. *Grounds of Rejection to be Reviewed on Appeal*

1. Whether Claims 23 - 44 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler (U.S. Patent 6,723,131) in view of Wironen et al. (U.S. 2003/0180262 A1).

2. Whether Claims 23 - 29, 32 and 35 - 40 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen and further in view of Erbe et al. (US 6736799 B1).

3. Whether Claims 23-27, 30-33, 36-38 and 40-43 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen and further in view of Willard et al. (US 4,846,174).

4. Whether Claims 23 - 44 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen and further in view of Erbe and Willard.

7. *Argument*

Each argument against the prior art rejection of record is set forth below.

Claims 23-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler (US 6723131) in view of Wironen et al. (US 2003/0180262 A1). Applicant submits that a *prima facie* showing of obviousness has not been established over Muschler in view of Wironen.

In assessing obviousness under 35 U.S.C. § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966); see also *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1734, 167 L.Ed.2d 705, 82 USPQ.2d 1385 (2007). Against this background the obviousness or nonobviousness of the subject matter is determined. *Id.* Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. *Id.*

The Examiner takes the position that Muschler teaches an apparatus for preparing a bone graft composite having various features of the claimed invention. The Examiner admits that Muschler does not teach an apparatus in which the filter membrane prevents aspirate passage while allowing air to pass through. However, the Examiner takes the position that Wironen teaches apparatuses for making bone graft composites in which one end has a filter membrane attached to prevent passage of bone paste components, aspirate or graft materials while expelling air from the tube, citing Wironen ¶0045. The Examiner interprets Wironen as teaching that it is desirable to remove air from the paste components before, during or after reconstitution is conducted, citing Wironen ¶0045. The Examiner concludes that at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the filter of Wironen in the apparatus of Muschler for the disclosed desirability for removing air from the bone graft composite material during mixing, citing Wironen ¶0045. The Examiner further concludes that at the time of the claimed invention, one of ordinary skill in the art would have

been motivated by Wironen to use a filter that prevents passage of bone paste components, aspirate or graft materials while expelling air with a reasonable expectation for successfully obtaining an apparatus for making bone graft composites.

The Examiner also admits that the combined teachings of Muschler and Wironen do not specifically teach an apparatus in which the aspirate is introduced via a first end having air expelled through the filter of the second end. The Examiner notes that Muschler teaches aspirate being loaded via the first end of a tube by means known in the art, and that the second end may contain a filter membrane. The Examiner further takes the position that Wironen teaches the advantages of using membranes that prevent passage of aspirate while allowing air to pass through, citing Wironen ¶0045. (Wironen makes no mention of aspirate, and applicant can find no such teaching in Wironen). The Examiner concludes that the combined teachings of Muschler and Wironen clearly suggest to one in the art to load the tube through one end while expelling air through the other.

The Examiner further admits that the cited references do not teach an apparatus in which the end caps have removable sealing caps, or wherein washers are used between the tube and end caps. In addition to the elements that the Examiner admits are not found in the cited references, applicant additionally points out that Muschler and Wironen do not teach various *other* features of the claimed invention, such as a filter member removably coupled to the leading end of the second end cap, a filter in the filter member, the filter configured to prevent bone marrow aspirate from passing therethrough while permitting air to pass through, the filter in fluid communication with the tube via the passage of the second end cap, nor aspirate and bone graft material in a tube apparatus having the foregoing features and arrangements. Thus, multiple

limitations of the claimed subject matter are not found in the cited art. To establish *prima facie* obviousness of a claimed invention, all the claimed limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). It has been held repeatedly that “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 165 USPQ 494,496 (CCPA 1970). In *KSR Int’l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 167 L.Ed.2d 705, 82 USPQ.2d 1385 (2007), the Supreme Court recently held that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.*, 127 S.Ct. at 1741. Accordingly, in the absence of a demonstration of claim elements being known in the prior art, *prima facie* obviousness is not established.

There is a gap in the teachings of the cited Muschler and Wironen references, and applicant respectfully suggests that when the cited references are carefully studied, they do not provide the required suggestion or teaching necessary to fill the gap. As will be discussed below, the cited references cannot be combined without destroying the stated objective of Muschler, the primary reference.

Nothing in Muschler suggests the need to remove air from the Muschler enriched bone graft, much less the need to remove air while preventing passage of bone marrow aspirate. Muschler specifically teaches away from this aspect of the claimed invention in at least two fundamental ways: (1) Muschler describes a screen or membrane that allows bone marrow aspirate to pass through Muschler’s matrix material and out of the chamber; and (2) the objective of Muschler is to provide a composite bone marrow graft material having an enriched population of progenitor cells compared to natural aspirate.

With regard to Muschler's screen or membrane, Muschler states: "Optionally, endcaps 14 can be provided with a screen or membrane 15 (see FIG. 8) ***effective to allow aspirate 20 to pass therethrough***, while retaining particles of matrix 10." (Muschler, Col. 7, lines 15-17; emphasis added). The only other place where Muschler mentions the membrane 15 is at Col. 10, lines 47-49, where Muschler states simply: "Optionally, the kit is provided with a porous biocompatible implanted substrate for use as a bone graft matrix, and porous membranes 15 to retain a matrix within the matrix container." Thus, Muschler describes the membrane 15 as being configured to ***allow bone marrow aspirate to pass therethrough***, and ***nowhere does Muschler suggest the need to configure the membrane to prevent passage of bone marrow aspirate while allowing passage of air***.

With regard to the objective of Muschler, the purpose of Muschler is to produce a "composite bone marrow graft material [having] an enriched population of progenitor cells." (Muschler, Col. 2, lines 40-41). In distinct contrast, applicant claims an apparatus that allows for removal of air while retaining the bone marrow aspirate in the tube. Removing air while retaining the bone marrow aspirate makes it impossible to increase the ratio of progenitor cells, thus destroying Muschler's objective. Key distinctions between Muschler and the claimed invention are highlighted at Muschler Col. 7, lines 39-Col. 8, line 11. Muschler specifically describes a process in which the bone marrow aspirate passes entirely through the matrix 10 in order to create the enriched graft material: "First loading syringe 28 is then plunged, delivering aspirate 20 into column 12 where ***aspirate 20*** flows through or contacts matrix 10 ***prior to being collected at the opposite end of column 12 in second loading syringe 29***." (Col. 7, lines 39-42; emphasis added). Muschler describes how the process of flowing the bone marrow aspirate

through the matrix 10 results in an enriched graft: "Progenitor cells advantageously and selectively adhere to the surface of matrix 10, and hence are retained within the matrix while excesses of other cells, such as blood cells and other marrow-derived nucleated cells, flow relatively freely through the matrix and are collected in second loading syringe 29." (Col. 7, lines 48-53). According to Muschler, after using the Muschler process of flowing the aspirate through the matrix, the resulting graft contains between a 2 to 8 fold increase in the ratio of progenitor cells compared to natural bone marrow aspirate. (Col. 7, line 61-Col. 8, line 3).

In the final office action, the Examiner took the position that applicant has failed to assert how the apparatus of Muschler is destroyed, and further stated that "the combined teachings of Muschler and Wironen suggest that air removal is desirable and that a filter to allow air passage and not BMA would benefit the apparatus of Muschler." Elaborating on the reasons discussed above, if Muschler were provided with a filter that allowed for passage of air but not aspirate, it would be impossible to achieve a 2-8 fold increase in the ratio of progenitor cells compared to natural bone marrow aspirate. Once the Muschler chamber was filled with an initial volume of aspirate, no further aspirate could be introduced into the chamber. Since the initial volume of aspirate contains the natural amount of progenitor cells found in bone marrow aspirate, and since the aspirate could not be expelled from the chamber and replaced with additional aspirate, the number of progenitor cells introduced into the chamber would not change, and the ratio of progenitor cells to natural bone marrow aspirate would consequently remain at the natural level. Since the purpose of Muschler's apparatus is to provide a 2 to 8 fold increase in the ratio of progenitor cells compared to natural bone marrow aspirate, (Muschler, Col. 7, line 61-Col. 8, line

3), modifying Muschler according to applicant's claimed teachings would not benefit Muschler, but would in fact destroy the intended function of Muschler.

In distinct contrast with Muschler, applicant's claims are directed to a tube that allows for expelling air from the tube while **retaining** the bone marrow aspirate in the tube. As noted above, because all of the bone marrow aspirate is retained in the tube, the ratio of progenitor cells to natural bone marrow aspirate does not change. Thus, the use of applicant's claimed tube will not result in a matrix having an increased ratio of progenitor cells. Furthermore, as discussed above, if Muschler were modified to include a filter that allowed air to pass through while retaining bone marrow aspirate, the stated function of Muschler (to increase the ratio of progenitor cells) would be destroyed. In *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 167 L.Ed.2d 705, 82 USPQ.2d 1385 (2007), the Supreme Court recognized that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *Id.*, 127 S.Ct. at 1740, citing *United States v. Adams*, 383 U.S. 39, 51-52, 86 S.Ct. 708, 15 L.Ed.2d 572 (1966). Applicant submits that Muschler teaches away from combining Muschler and Wironen in the manner of the claimed invention, since doing so would destroy Muschler's objective of increasing the ratio of progenitor cells.

Applicant's specification establishes that applicant identified the drawbacks of the Muschler design and provided the proposed solution. In applicant's specification, applicant discussed the features of Muschler with reference to Muschler's U.S. Patents 5,824,084 and 6,049,026¹ as follows:

The [Muschler] bone graft is prepared by providing a bone marrow aspirate suspension and passing the bone marrow aspirate suspension through a

¹ When applicant filed the specification, the cited Muschler reference, U.S. Patent 6,723,131, had not yet issued.

porous, biocompatible, implantable substrate resulting in a composite bone graft having an enriched population of connective tissue progenitor cells that collects in an effluent collector separate from the mixing chamber (i.e., container 14).

(Applicant's specification, p. 6, line 29-p. 7, line 2). After explaining the foregoing features of Muschler, applicant noted that applicant's invention "offers flexibility by allowing the composite to be mixed (i.e infused) in the operating room . . . using the patient's own healing potential in the form of bone marrow aspirate, blood, or platelet concentrate." (Applicant's specification, p. 7, lines 5-7). As a key feature of applicant's apparatus, applicant noted: "The filter on the second end of the tube allows air to be expelled from the tube as it is filled with the bone marrow aspirate. However, the filter should be sufficiently dense to *prevent leakage of the bone marrow aspirate.*" (Applicant's specification, p. 7, lines 21-23; emphasis added). Thus, directly counter to the teaching of Muschler, applicant teaches providing a filter on the second end that does not allow bone marrow aspirate to pass through. The teaching to provide such a filter, and the resulting function, is provided in applicant's specification, not in the cited prior art.

The claimed apparatus, which has been selling successfully, allows a surgeon to prepare a useful bone marrow aspirate derived bone graft material quickly and efficiently in the operating room. In actual practice, applicant has found that a bone marrow aspirate impermeable filter member on the second or leading end of the tube is an important feature of the apparatus because it enables the tube to be filled with as much bone marrow aspirate as possible, which in turn exposes the bone graft material to as much bone marrow aspirate as possible. Fluid pressure created in the tube during expulsion of air through the filter creates back flow, which further circulates bone marrow aspirate within the bone graft material. (See Applicant's Figure 7). Without a filter, the bone marrow aspirate would simply flow across the bone graft material

during filling, in which case the bone graft material could only absorb bone marrow aspirate components that flow past the bone graft material. With the filter on the leading end of the tube, all of the bone marrow aspirate is retained in the tube and, after a selected period of coagulation, a more uniformly shaped piece of composite bone graft material is obtained. The foregoing features are particularly useful in the operating room, because they enable formation of a composite bone marrow aspirate bone graft material using relatively simple instruments and methods, and within a time frame suitable to surgical procedures. As discussed in applicant's specification, the claimed apparatus enables the foregoing functions.

In contrast with Muschler, and contrary to the Examiner's position, Wironen makes no mention of the use of a bone marrow aspirate. Consequently, Wironen makes no suggestion of the desirability of retaining bone marrow aspirate while expelling air. Rather, Wironen is concerned with the problem of preserving and storing bone pastes. As explained in ¶0003 of Wironen, "While current methods of utilizing bone paste have shown promise, there is a constant need for devising new, cost-effective techniques of storing and preserving bone paste and other biomedical substances, which, in turn, will increase their usefulness and adaptability to medical applications." The preservation and storage of bone pastes is an entirely different function than that of the claimed apparatus. As discussed above, the claimed apparatus allows a surgeon to efficiently prepare a useful bone marrow aspirate derived bone graft material in the operating room for use *during* the operation. Preserving the bone graft is not the object of the claimed invention, and it is unclear how doing so would provide a benefit, since the bone marrow aspirate naturally solidifies (coagulates) around the bone graft material and becomes more firm over time. (Specification, p. 13, lines 16-20).

In the few places where Wironen discusses the expulsion of air from a syringe, there is no suggestion that expulsion of air can be used to improve the process of forming a composite bone graft material from bone marrow aspirate. Of the four places where Wironen mentions “air,” only one place describes expelling air from the syringe. ¶0022 is merely a brief description of drawing Figure 10. ¶0034 is concerned not with expelling air but rather with minimizing “dead” space between the two syringes, thereby alleviating unwanted air bubbles. Thus, ¶0034 is concerned with minimizing air bubbles rather than with expelling air. ¶0043 describes a relatively complicated method of removing air from a bone paste using three syringes joined by a three-way stop valve. Finally, ¶0045 provides a detailed description of Figure 10, which depicts a syringe in which removal of air is facilitated by providing an aperture in the plunger of the syringe. In Wironen Figure 10, the plunger 1000 has an aperture 1010 at its end 1020 in contact with paste components, wherein the aperture communicates with the other end of the plunger 1030 through a channel 1040 defined within the plunger 1000. Preferably, to prevent escape of paste components or reconstitution fluid, the aperture is covered with an air-permeable membrane or filled with an air-permeable plug. As the plunger is pushed against the contents of the syringe, the pressure caused thereby acts to push the air contained in the contents through the aperture and to expel the air out of the syringe. (See Wironen, ¶0045). The structure of Wironen Figure 10 differs significantly from that of the claimed invention. The suggestion to combine references must not require substantial reconstruction or redesign to arrive at the claimed invention. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (C.C.P.A. 1959). Notably absent from Wironen is any reason or motivation for the desirability of retaining bone marrow aspirate while expelling air.

In *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 167 L.Ed.2d 705, 82 USPQ.2d 1385 (2007), the Supreme Court explained why it is important to identify a reason that would have prompted a person of ordinary skill in the art to combine elements in the manner of the claimed invention:

[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Id. at 1741. In the present case, applicant maintains that a sufficient reason has not been provided, because the proposed combination would destroy the function of the Muschler reference. Under the circumstances, it is respectfully suggested that a *prima facie* showing of obviousness has not been established.

The Examiner has taken the position that applicant is arguing the Muschler and Wironen references separately, and concluded that one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. Applicant disagrees with this characterization of applicant's position. The *Graham* test, as well as §103(a), requires an analysis of the scope and content of the prior art, and the differences between the prior art and the claimed invention. While it is certainly necessary to discuss the two references separately in order to conduct the *Graham* analysis, applicant has also provided various reasons why the differences between the references remove any basis for concluding that a person of ordinary skill at the time of the invention would have had a reason or motivation to combine the

references in the manner of the claimed invention. It is not the references that are being argued separately, but rather applicant's specification that is being used to combine separate references through hindsight reconstruction.

In the rejection under Muschler over Wironen, the Examiner also maintains a longstanding attempt to incorporate missing elements (end caps having removable sealing caps; washers between the tube and end caps) through applicant's previous admission, which applicant made in response to a five-way restriction requirement. Applicant has raised several objections to the Examiner's reliance on applicant's admission as a basis for supplying elements that are admittedly missing from the cited references. First, applicant respectfully submits that applicant's admission, which was made in response to the five-way restriction requirement, is being taken out of context and is now moot. Second, in relying on applicant's admission, the Examiner may be losing sight of the determinative issue of obviousness. Third, applicant does not believe that the Examiner's position has been explained to the point where applicant would be able to adequately respond, much less to the level necessary to establish a prima facie showing.

The admission in question was made long ago in response to a five-way restriction requirement involving five sets of claims that were very similar to one another. Because the five claim sets were very similar, applicant was of the view that the Patent Office had not met its burden of establishing that the application claimed five independent and distinct inventions. Rather than traverse the restriction requirement, applicant elected to admit that the claims were obvious over each other so that all five sets of similar claims could be examined in the same

application. In making the admission, applicant specifically noted the following concerns about the five-way restriction requirement:

In view of the similarity in the structure and elements of the claims and *applicant's concern that a showing of distinctiveness has not been made*, applicant admits that the claimed inventions would have been obvious over each other within the meaning of 35 U.S.C. 103. Therefore restriction between Inventions I, II, III, IV and V should not be required. See MPEP § 803; *In re Lee*, 199 USPQ 108 (Comm'r Pat. 1978).

Based on the prior art, it appears to applicant that claims of the type presented in the present application are routinely classified in Class 623, Subclass 16 or 23 (see e.g. U.S. 5,824,084; U.S. 6,049,026). It is not clear to applicant why the claims of the present application would be classified in either Class 424 or 435, as suggested by the Examiner in the foregoing claim groupings. Applicant is of the view that the inventions as claimed have not achieved a separate classification, that the field of search is the same, that search and examination of all of the claims can be made without serious burden, and that the Patent Office has not met its burden of demonstrating distinctiveness between the five sets of claims. It also appears to applicant that February 14, 2006 restriction requirement did not attempt to make a showing of distinctiveness between the following inventions: I and III; I and V; and IV and V. However, as noted above, restriction should not be required in view of applicant's admission.

(Applicant's September 1, 2006 Response, pp. 5-6; emphasis added).

Applicant later decided to cancel the original five sets of similar claims and pursue a single set of claims. Nonetheless, the Examiner has maintained that applicant's admission renders the current claims obvious by supplying elements that are missing from the cited references. Applicant has been of the view that the statement is being taken out of the context of the procedural issue to which the statement was directed, and that in any event, the admission is moot now that applicant has elected to pursue a single set of claims. When applicant made the admission, applicant was attempting to find an efficient way to deal with what appeared to applicant to be an extreme five-way restriction requirement. In making the admission, applicant specifically noted its concern that a showing of distinctiveness had not been made. (See pp. 5-6

of applicant's response, quoted above). This is clearly not a situation where applicant was attempting to short-cut restriction practice and put an undue burden on the Examiner, but rather one where applicant genuinely did not believe that the requisite showing of distinctiveness had been made, and decided that the most efficient way to deal with the issue was to make a procedural admission. Applicant was certainly incorrect in believing that the admission would be an efficient way to deal with the restriction. Nonetheless, applicant respectfully suggests that its claims should be examined on the merits relative to the prior art, not based on applicant's attempt to resolve a genuine disagreement over a restriction requirement by using a standard and longstanding procedural practice.

The closest analogous case appears to be *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392, 1394 (Fed. Cir. 1991), in which the Federal Circuit held that a terminal disclaimer "is not an admission of obviousness of the later filed claimed invention in light of the earlier filed disclosure. . . . In legal principle, the filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection." *Id.* at 1394. Like a terminal disclaimer filed in response to an obviousness type double patenting rejection, applicant's statement was directed to the procedural question of whether a five-way restriction was proper, not to the substantive merits of a pending rejection. At the time of the admission, applicant did not know what prior art the Examiner would eventually cite, and applicant therefore certainly did not admit that the claims were obvious over the references that are now being cited. Applicant also could not foresee how the claims would be amended in the future.

Needless to say, applicant did not admit that the current set of claims are obvious over the claims that were pending at the time of the restriction requirement.

However, even if applicant's statement is not considered moot under the circumstances presented, applicant remains unclear as to the Examiner's position, although applicant agrees that the Examiner attempted to elaborate on the position following withdrawal of applicant's first appeal. As best applicant can understand the Examiner's position, the Examiner is of the view that: (1) because applicant's original claims mentioned end caps and removable sealing caps; (2) because applicant's original five sets of claims were directed to bone graft material, methods for making the material, and an apparatus for housing/preparing the material; and (3) because applicant admitted that the original five sets of claims were obvious over one another in order to address a five-way restriction requirement, *any* claims that mention these components are rendered obvious, without any need to consider the arrangements under which these components are claimed in the previous or existing claims, nor the differences between the claimed arrangements and the actual prior art. If the foregoing is the Examiner's position, then applicant does not believe that this is sufficient to establish a *prima facie* showing of obviousness over Muschler in view of Wironen, nor to adequately appraise applicant of the grounds of the obviousness showing. As MPEP ¶ 2142 makes clear, as part of the burden of making a *prima facie* showing, the Examiner must present reasoning supporting the obviousness rejection. See also *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986); *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443, 1447 (Fed. Cir. 1992). Although applicant agrees that the Examiner has attempted to clarify its position following the withdrawal of applicant's first appeal, applicant respectfully suggests that it has not been given a sufficient explanation. Under the current record,

applicant simply does not have enough information to attempt to adequately respond to the Examiner's position that applicant's admission renders the claims obvious. Applicant again suggests that the focus of the obviousness determination should be on the teachings of the prior art, not on statements that were made in a different context (i.e. in response to a restriction requirement).

Claims 23 - 29, 32 and 35 - 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen and further in view of Erbe et al. (US 6736799 B1).

The Examiner takes the position that at the time of the invention, one of ordinary skill in the art would have been motivated to combine the teachings of Muschler and Wironen, based on the same reasoning discussed above. Applicant incorporates by reference its previous position concerning the proposed combination of Muschler and Wironen. Accordingly, for the same reasons discussed above, applicant does not agree that the underlying arrangement of the claimed invention is obvious over Muschler and Wironen.

The Examiner admits that the Muschler and Wironen references do not teach the apparatus wherein the end caps have removable sealing caps. The Examiner relies on Erbe to supply the missing elements. The Examiner takes the position that at the time of the claimed invention, the end caps of apparatuses for making bone graft composites were commonly sealed in the art. In support, the Examiner cites Erbe as teaching an apparatus for making bone composite materials wherein the end caps are closed (or sealed) to seal the material chamber (or tube with graft material) (col.3, line 9-25, claims). The Examiner further admits that Erbe does not expressly teach the sealing cap in addition to the end cap, but takes the position that the

reference certainly suggests to one in the art the desire to seal the graft tubes. The Examiner concludes that at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice, as evidenced by Erbe, to include a sealing cap on the apparatus of Muschler with a reasonable expectation for successfully obtaining an apparatus effective to prepare a bone graft composite.

In addition to the Examiner's admission that Erbe does not expressly teach a sealing cap in addition to an end cap, applicant further notes that Erbe (as well as Muschler and Wironen) also does not supply various other elements and arrangements of the claimed invention, such as a filter member removably coupled to the leading end of the second end cap, a filter in the filter member, the filter in the filter member configured to prevent bone marrow aspirate from passing therethrough while permitting air to pass through, the filter in fluid communication with the tube via the passage of the second end cap, nor aspirate and bone graft material in a tube apparatus having the foregoing features and arrangements. These claimed arrangements of elements provide useful advantages over the prior art, for the reasons discussed above. In *KSR*, the Supreme Court cautioned that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *Id.*, 127 S.Ct. at 1742, citing *Graham*, 383 U.S. at 36. In the present application, applicant's disclosure, not the cited references, provides the reason and motivation for the claimed arrangement. In view of the missing elements and arrangements, and in view of the fact that the proposed modifications would destroy the function of the primary Muschler reference, applicant respectfully suggests that a *prima facie* showing of obviousness has not been established over Muschler in view of Wironen and further in view of Erbe.

Claims 23-27, 30-33, 36-38 and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen and further in view of Willard et al. (US 4,846,174).

The Examiner takes the position that at the time of the invention, one of ordinary skill in the art would have been motivated to combine the teachings of Muschler and Wironen, based on the same reasoning discussed above. Applicant incorporates by reference its previous position concerning the proposed combination of Muschler and Wironen. Accordingly, for the same reasons discussed above, applicant does not agree that the underlying arrangement of the claimed invention is obvious over Muschler and Wironen.

The Examiner admits that the references do not teach the apparatus wherein washers are used between the tube and end caps. The Examiner relies upon Willard to supply the missing elements. The Examiner interprets Muschler as teaching end caps that are removable from the tube via threaded connections, or any other known connection. The Examiner concludes that at the time of the claimed invention, it was known to include washers between caps and threaded connections for their aid in equalizing pressure distribution, securing placement and ensuring air tightness. In support, the Examiner interprets Willard as teaching columnar tubes wherein a threaded end has a removable cap and washer placed in between to secure the assembly. The Examiner concludes that at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice, as evidenced by Willard, to include a washer in the apparatus of Muschler with a reasonable expectation for successfully obtaining an apparatus effective to prepare a bone graft composite.

Reiterating previous points, applicant notes that Willard (as well as Muschler and Wironen) does not supply various other elements and arrangements of the claimed invention, such as a filter member removably coupled to the leading end of the second end cap, a filter in the filter member, the filter in the filter member configured to prevent bone marrow aspirate from passing therethrough while permitting air to pass through, the filter in fluid communication with the tube via the passage of the second end cap, nor aspirate and bone graft material in a tube apparatus having the foregoing features and arrangements. These claimed arrangements of elements provide useful advantages over the prior art, for the reasons discussed above. Applicant also notes that Willard is directed to a dilating guide wire for use in percutaneous transluminal angioplasty. It is relevant that none of the cited references teaches using a washer in an apparatus for preparing a bone graft material. This factor points away from a reason or motivation to combine the teachings of three references in order to supply the various missing elements and arrive at the arrangement of the claimed invention.

In applicant's view, applicant's disclosure provides the reason and motivation for the claimed arrangement. In view of the missing elements and arrangements, and in view of the fact that the proposed modifications would destroy the function of the primary Muschler reference, applicant respectfully suggests that a prima facie showing of obviousness has not been established over Muschler in view of Wironen and further in view of Willard.

Claims 23 - 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen and further in view of Erbe and Willard.

The Examiner takes the position that at the time of the invention, one of ordinary skill in the art would have been motivated to combine the teachings of Muschler and Wironen, based on the same reasoning discussed above. Applicant incorporates by reference its previous position concerning the proposed combination of Muschler and Wironen. Accordingly, for the same reasons discussed above, applicant does not agree that the underlying arrangement of the claimed invention is obvious over Muschler and Wironen.

The Examiner admits that the references do not teach an apparatus wherein the end caps have removable sealing caps, but concludes, for the same reasons discussed above, that at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice, as evidenced by Erbe, to include a sealing cap on the apparatus of Muschler with a reasonable expectation for successfully obtaining an apparatus effective to prepare a bone graft composite. Applicant incorporates by reference its previous position concerning the proposed combination of Muschler, Wironen and Erbe.

The Examiner further admits that the references do not teach an apparatus wherein washers are used between the tube and end caps, but concludes, for the same reasons discussed above, that at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice, as evidenced by Willard, to include a washer in the apparatus of Muschler with a reasonable expectation for successfully obtaining an apparatus effective to prepare a bone graft composite. Accordingly, applicant incorporates by reference its previous position concerning the proposed combination of Muschler, Wironen and Erbe.

Reiterating previous points, applicant notes that the cited references do not supply various elements and arrangements of the claimed invention, such as a filter member removably

coupled to the leading end of the second end cap, a filter in the filter member, the filter in the filter member configured to prevent bone marrow aspirate from passing therethrough while permitting air to pass through, the filter in fluid communication with the tube via the passage of the second end cap, nor aspirate and bone graft material in a tube apparatus having the foregoing features and arrangements.

As previously noted, applicant's disclosure provides the reason and motivation for the claimed arrangement. In applicant's view, the Examiner's conclusion of obviousness includes knowledge gleaned from applicant's disclosure. In view of the missing elements and arrangements, and in view of the fact that the proposed modifications would destroy the function of the primary Muschler reference, applicant respectfully suggests that a *prima facie* showing of obviousness has not been established over Muschler in view of Wironen and further in view of Erbe and Willard.

For the foregoing reasons, it is respectfully submitted that a *prima facie* case of obvious has not been established. The cited references lack the arrangement and a number of elements of the claimed invention. Combining the references in the manner suggested by the Examiner would destroy the stated function of the primary reference, Muschler, which is to provide a bone graft having an enriched population of progenitor cells by passing bone marrow aspirate through a matrix. Applicant's specification is being used to supply the required suggestion to combine, resulting in hindsight reconstruction of the claimed invention. Accordingly, applicant respectfully requests that the Board overturn the rejections of record.

8. *Claims Appendix*

An appendix containing a copy of the claims involved in the appeal is attached below.

9. *Evidence Appendix*

None.

10. *Related Proceedings Appendix*

None.

CONCLUSION

In view of the foregoing arguments, Appellant respectfully submits that Claims 23-44 are patentable over the cited references. A decision from the Board of Patent Appeals and Interferences reversing the final rejection of the pending claims is therefore earnestly solicited.

Respectfully submitted,

/Shawn D. Sentilles/
Shawn D. Sentilles
Registration No. 38,299

CUSTOMER NO. 37902
WRIGHT MEDICAL TECHNOLOGY, INC.
5677 Airline Road
Arlington, TN 38002
Telephone: 901-867-4314

CLAIMS APPENDIX

1-22. (Cancelled)

23. (Previously presented) An apparatus for preparing a bone graft composite comprising a bone graft material and a bone marrow aspirate, the apparatus comprising:

a tube having a first open end and a second open end;

a first end cap removably coupled to said first open end, said first end cap having a passage therethrough to allow fluid communication between a bone marrow aspirate delivery member and said tube, a trailing end of said first end cap configured for selective attachment to a bone marrow aspirate delivery member;

a second end cap removably coupled to said second end, said second end cap having a passage therethrough to allow fluid communication between said tube and a filter, a leading end of said second end cap configured for selective attachment of a filter;

a filter member removably coupled to said leading end of said second end cap;

a filter in said filter member, said filter configured to prevent bone marrow aspirate from passing therethrough while permitting air to pass therethrough, said filter in fluid communication with said tube via said passage of said second end cap; and

a bone graft material in the tube.

24 (Previously presented) The apparatus of claim 23, wherein said bone graft material is selected from the group consisting of calcium sulfate, calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix.

25. (Previously presented) The apparatus of claim 23, wherein said bone graft material comprises tri-calcium phosphate.

26. (Previously presented) The apparatus of claim 23, wherein said bone graft material is porous to bone marrow aspirate.
27. (Previously presented) The apparatus of claim 23, wherein said bone graft material comprises a plurality of small pieces of bone graft material.
28. (Previously presented) The apparatus of claim 23, further comprising said first end cap sealed by a removable first sealing cap on a trailing end of said first end cap.
29. (Previously presented) The apparatus of claim 28, further comprising said filter member sealed by a removable second sealing cap on a leading end of said filter member.
30. (Previously presented) The apparatus of claim 23, further comprising a first washer disposed between said first end cap and said first end of said tube.
31. (Previously presented) The apparatus of claim 30, further comprising a second washer disposed between said second end cap and said second end of said tube.
32. (Previously presented) The apparatus of claim 25, wherein said bone graft material comprises a plurality of small pieces of bone graft material.
33. (Previously presented) The apparatus of claim 32, further comprising a first washer disposed between said first end cap and said first end of said tube, and a second washer disposed between said second end cap and said second end of said tube.
34. (Previously presented) The apparatus of claim 33, further comprising said first end cap sealed by a removable first sealing cap on a trailing end of said first end cap.
35. (Previously presented) The apparatus of claim 24, further comprising said filter member sealed by a removable second sealing cap on a leading end of said filter member.

36. (Previously presented) The apparatus of claim 23, further comprising bone marrow aspirate in said tube, said bone marrow aspirate having been introduced into said tube through said first end of said tube, and air having been expelled through said filter of said filter member to facilitate introduction of said bone marrow aspirate into said tube.

37. (Previously presented) The apparatus of claim 36, wherein said bone marrow aspirate has been allowed to coagulate in said tube while in contact with said bone graft material.

38. (Previously presented) The apparatus of claim 36, wherein said bone graft material is substantially saturated with said bone marrow aspirate.

39. (Previously presented) The apparatus of claim 36, further comprising coupling a second sealing cap to said filter member to thereby provide a relatively air tight environment after air has been expelled from the tube.

40. (Previously presented) The apparatus of claim 36, wherein said bone graft material comprises tri-calcium phosphate.

41. (Previously presented) The apparatus of claim 40, further comprising a first washer disposed between said first end cap and said first end of said tube.

42. (Previously presented) The apparatus of claim 41, further comprising a second washer disposed between said second end cap and said second end of said tube.

43. (Previously presented) The apparatus of claim 42, wherein said trailing end of said first end cap configured for attachment to a bone marrow aspirate delivery member is configured for attachment to a syringe.

44. (Previously presented) The apparatus of claim 43, further comprising coupling a second sealing cap to said filter member to thereby provide a relatively air tight environment after air has been expelled from the tube.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.